K100599

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

CAS Fixation Pins

Applicant: Zimmer CAS
75 Queen Street, suite 3300
Montreal, Quebec
Canada, H3C 2N6
Tel.: 514 861 4074
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APR - 5 2010

Contact Person: Christopher McLean

Date Summary Prepared: March 1, 2010

Device Trade Name: CAS Fixation Pins

Device Classification Name: Stereotaxic Instrument (84 HAW); 21 CFR § 882.4560

Predicate Device:
Navitrack® System – Partial Hip Resurfacing Universal from Zimmer CAS (transferred from Orthosoft Inc.), 510(k) # K071929

Device Description:
CAS Fixation Pins are threaded bone pins similar to Steinmann pins. They are used to temporarily fixate locational reference instruments to bones in order to reference their location in Computer Assisted Surgery (CAS) systems.

Indications for Use / Intended Use:
CAS Fixation Pins from Zimmer CAS are intended for use as temporary bone fixation pins to attach orthopedic surgical instruments to bones in order to allow referencing their relative locations as required in the use of computer assisted surgery systems. Their specific uses and indications including their method of use and attachment sites are as specified in the computer assisted surgery system that involves their use.

Technological Comparisons to the Predicates:
The difference between the proposed and predicate pins is that the proposed pins will be provided sterile packaged while the predicate ones are provided non-sterile to be sterilized by the user facility. The proposed method of sterilization is radiation while the labeled user method for the predicate is the common steam sterilization cycle used in hospital settings. The proposed and predicate pins are otherwise identical.

Performance Data:
The proposed pin will be provided sterile using validated sterilization and packaging methods with an SAL of 10^{-6}.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the proposed CAS Fixation Pins are substantially equivalent to the fixation pins of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 5 2010

Zimmer CAS
% Mr. Christopher McLean
Associate Director
Quality & Regulatory Affairs
75 Queen Street, Suite 3300
Montreal, Quebec, Canada H3C 2N6

Re: K100599
Trade/Device Name: CAS Fixation Pins
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 01, 2010
Received: March 03, 2010

Dear Mr. McLean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K100599

Device Name: CAS Fixation Pins

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CAS Fixation Pins from Zimmer CAS are intended for use as temporary bone fixation pins to attach orthopedic surgical instruments to bones in order to allow referencing their relative locations as required in the use of computer assisted surgery systems. Their specific uses and indications including their method of use and attachment sites are as specified in the computer assisted surgery system that involves their use.

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100599